

A LANCET DEVICE

BACKGROUND OF THE INVENTION

Claim of Priority

The present application is a continuation-in-part application of previously filed, now pending application having Serial No. 10/134,995, filed on April 29, 2002.

Field of the Invention

The present invention relates to a lancet device preferably configured to provide a single use, and in all embodiments configured to substantially shield and protect a piercing tip thereof before and after use, while providing for accurate and effective piercing engagement of a patient's skin when appropriate. Furthermore, the present lancet device does not require complex and/or difficult to manipulate cocking and is structured such that the device is rendered in-operative after a single use.

DESCRIPTION OF THE RELATED ART

Lancets are commonly utilized instruments which are employed both in hospitals and other medical facilities, as well as by private individuals, such as diabetics, in order to prick or pierce a patient's skin, typically on a finger of a patient,

1 thereby leading to the generation of a blood sample which can be
2 collected for testing. Because of the wide spread use of such
3 lancets, there are a variety of lancet devices which are
4 available for utilization by patients and/or practitioners in a
5 variety of different circumstances.

6 For example, a typical lancet may merely include a housing
7 with a sharp piercing tip that is pushed into the patient's
8 skin. More commonly, however, lancet devices, which house a
9 piercing tip and/or a lancet, have been developed which
10 effectively encase and fire the lancet into the patient's skin,
11 thereby eliminating the need for the person taking the sample to
12 actually push the lancet tip into the skin.

13 Within the various types of specialized lancet devices, one
14 variety are typically configured for multiple and/or repeated
15 uses, while another category is particularly configured for
16 single use, after which the entire device is disposed of.
17 Looking in particular to the single use, disposable lancet
18 devices, such devices typically include a housing which contains
19 and directs or drives a piercing tip into the patient's skin,
20 and which is disposed of along with the used lancet. Naturally,
21 so as to make such disposable devices cost effective for
22 frequent use, such devices tend to be rather simplistic in
23 nature providing only a sufficient mechanism for firing, and not
24 overly complicating the design so as to minimize that cost.

25 While existing single use devices are generally effective

1 for achieving the piercing of the skin required for effective
2 operation, such single use, disposable devices typically do not
3 incorporate a large number of safety features to ensure the safe
4 use and disposal of the device. For example, one primary area
5 of safety which must be addressed with all lancet devices
6 pertains to the purposeful and/or inadvertent reuse of a
7 contaminated lancet. Unfortunately, most currently available
8 single use lancet devices are configured such that after a use
9 thereof has been achieved, it is possible for a patient to re-
10 cock the device, thereby allowing for a subsequent,
11 inappropriate use.

12 As a result, it would be highly beneficial to provide a
13 single use lancet device which is substantially compact and
14 disposable, can be manufactured in a substantially cost
15 effective manner, and which nevertheless is substantially safe
16 to utilize, affirmatively preventing re-use, once contaminated.

17 A further drawback associated with conventionally employed
18 single use lancet devices is that they can often be difficult
19 and/or complicated for elderly and/or impaired individuals to
20 manipulate in order to achieve effective use. In particular,
21 such existing devices often require a user to perform a number
22 of different actions, including one to cock and thereby prepare
23 the device for use, and another to actually fire the device. As
24 can be appreciated, those procedures, even in the simplest form,
25 can sometimes be complex and/or difficult to effectively achieve

1 on a small compact device by certain individuals, and especially
2 those individuals performing self testing who necessarily only
3 have one hand to use to manipulate the device. Indeed, to avoid
4 these complexities, some manufactures have turned to the use of
5 pre-cocked and ready to use devices, however, this can often
6 result in misfires and/or pre-fires of the lancet such that a
7 certain of percentage of the lancet devices are not usable.

8 As a result, it would also be beneficial to provide a
9 lancet device, which whether single use and/or multiple use,
10 could be very simplistic and effective to employee, not
11 requiring a series of often complex activities to be perform in
12 order to prepare the lancet for use and in order to actually
13 utilize the lancet. Still, however, such a device should not
14 comprise safety in the prevention of inadvertent use and/or re-
15 use in exchange for the simplistic use, but rather should
16 effectively coordinate all such beneficial characteristics. It
17 would also be beneficial such a device could be effectively and
18 cost effectively manufacture so as to make it available and
19 affordable to a large variety of users, including home users.

20 21 SUMMARY OF THE INVENTION

22 The present invention relates to a lancet device, and
23 preferably a single use lancet device, utilized so as to
24 effectively pierce a patient's skin and result in bleeding for
25 subsequent sample collection. The lancet device of the present

1 invention preferably includes a housing having an at least
2 partially open interior. Furthermore, a lancet is movably
3 disposed relative to the housing and includes a piercing tip
4 which ultimately will penetrate the patient's skin. Similarly,
5 a biasing assembly is interposed between the lancet and the
6 housing. The biasing assembly engages the lancet and functions
7 to urge the lancet into its piercing orientation, when
8 appropriate.

9 The lancet device of the present invention also includes a
10 cocking seat. The cocking seat is structured to engage the
11 lancet and retain the lancet against the force of the biasing
12 assembly so as to establish a potential energy of the biasing
13 assembly. In the preferred embodiment, the user's finger and/or
14 another body part which is to be pierced, engages the cocking
15 seat and thereby pushes the cocking seat and the lancet until it
16 ultimately engages a release assembly that extends into the
17 housing. In alternate embodiments, the cocking seat is
18 integrally or separately disposed relative to the housing to
19 retain the lancet against the force of a biasing element until
20 released by an actuatable release assembly. The release assembly
21 is structured to disengage the lancet from the cocking seat such
22 that the potential energy of the biasing assembly drives the
23 piercing tip of the lancet at least temporarily into its
24 piercing orientation. As a result, in one illustrated
25 embodiment, as the cocking seat moves the lancet, simultaneously

1 cocking it and moving it into its engaging relation with the
2 release element for effective actuation and firing thereof to
3 pierce the skin of the patient, while in another embodiment, the
4 lancet device is "pre-cocked".

5 These and other features and advantages of the present
6 invention will become more clear when the drawings as well as
7 the detailed description are taken into consideration.

8
9 BRIEF DESCRIPTION OF THE DRAWINGS

10 For a fuller understanding of the nature of the present
11 invention, reference should be had to the following detailed
12 description taken in connection with the accompanying drawings
13 in which:

14 Figure 1 is a side cross-sectional view of a preferred
15 embodiment of the lancet device of the present invention in an
16 un-used orientation;

17 Figure 2 is a side cross-section view of the embodiment of
18 Figure 1 in a substantially cocked and immanent to release
19 orientation;

20 Figure 3 is a side cross-sectional view of a further
21 embodiment of the lancet device of the present invention;

22 Figure 4 is an exploded view of the lancet device and
23 cocking seat of a preferred embodiment of the present invention;

24 Figure 5 is a side cross-section view of still another
25 embodiment of the lancet device of the present invention

1 illustrating a re-usable configuration thereof; and

2 Figure 6 is a side cross-section view of another embodiment
3 of the lancet device of the present invention illustrating a
4 fixed cocking seat.

5 Like reference numerals refer to like parts throughout the
6 several views of the drawings.

7
8 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

9 Shown throughout the Figures, the present invention is
10 directed towards a lancet device, generally indicated as 10. In
11 one embodiment of the present invention, as illustrated in
12 Figures 1 through 3 and 6 the lancet device 10 is preferably a
13 single use device such that after it is utilized for the first
14 and only time it is configured so as to prevent subsequent use.
15 Ultimately, however, as illustrated in Figure 5, a re-usable
16 configuration may be provided.

17 Looking specifically to the Figures, the lancet device of
18 the present preferably includes a housing 20. The housing 20
19 includes an at least partially open interior 22 and can be made
20 of any variety materials, but preferably will be formed of a
21 molded plastic type material for ease of manufacture and
22 minimization of cost. Also in the preferred embodiment, the
23 housing 20 preferably includes an open end 26, which may
24 represent a general front of the lancet device 10, and may
25 include any variety of axial configurations, including a square,

1 triangle, oval, circle, etc., although a generally elongated,
2 longitudinal configuration as illustrated in the Figures is
3 preferred in conjunction therewith.

4 The lancet device 10 further includes a lancet 40 movably
5 disposed at least partially within the housing 20 and including
6 a piercing tip 42. In the single use embodiment of Figures 1
7 through 3 and 6 the lancet 40 is a single integral unit as
8 shown. Alternatively, as illustrated in the embodiment of
9 Figure 5, what is referred to as a lancet in the claims may
10 include a lancet body 40' from which the piercing tip 42
11 extends, as well as a lancet receiving assembly 41, into which
12 the lancet body 40' is disposed for movable retention. In such
13 an embodiment, each time the lancet device 10 is to be re-used,
14 a new lancet body 40' with piercing tip 42 is disposed within
15 the lancet receiving assembly 41. In either embodiment,
16 however, the lancet is movably disposed within the housing 20.

17 Preferably the lancet engages a biasing assembly also
18 preferably disposed within the housing 20. In the illustrated
19 preferred embodiments, the biasing assembly includes a biasing
20 element 50 such as a metal or plastic spring. Preferably, the
21 biasing element 50 is interposed between the lancet 40 and a
22 rear end 55, 55' of the housing 20. The rear end 55, 55' may be
23 unitary or separate from the housing 20. Moreover, positioned
24 so as to engage the lancet 40 and retain it under the tension of
25 the biasing assembly 50 is a cocking seat 30. In particular,

1 the cocking seat 30 is structured to engage the lancet 40 and
2 retain the lancet 40 against a force of the biasing assembly 50
3 so as to maintain a potential energy of the biasing assembly 50.
4 In some illustrated embodiments, and as best seen in Figure 2,
5 the cocking seat 30 urges the lancet 40 towards the rear end of
6 the lancet housing 20, thereby resulting in a compression of the
7 biasing assembly 50 and an increase in the potential energy
8 thereof. Further, so as to maintain effectively appropriate
9 alignment of the lancet and the cocking seat 30 as they are
10 moving relative to the housing 20, in the preferred embodiment,
11 a guide track assembly 24, 32 may be provided between the
12 cocking seat 30 and the housing 20.

13 In the preferred, illustrated embodiments, an engagement
14 assembly 34, 45 is provided and preferably interposed between
15 the cocking seat 30 and the lancet 40 so as to maintain moving
16 engagement between the lancet 40 and the cocking seat 30 until
17 they are disengaged, as will be described. In the illustrated
18 embodiments, the engagement assembly includes an engagement
19 element 45 that extends from lancet 40 into effectively
20 retained, engaging relation with a retention lip 34 on the
21 cocking seat 30. As a result, as the cocking seat 30 moves
22 inward towards the rear end 55 of the housing 20, the effective
23 engagement between the engagement element 45 and the retention
24 lip 34 results in movement of the lancet 40 in unison with the
25 cocking seat 30. In this regard, it is understood that a

1 variety of different engagement assemblies, including one in
2 which the engagement element extends from the cocking seat into
3 engagement with a corresponding retention lip on the lancet, may
4 also effectively be provided, the engagement assembly being
5 configured so as to provide for effective substantially,
6 although not necessarily completely, unitary movement between
7 the lancet 40 and the cocking seat 30 until effective release
8 thereby, as will be described. Further, in yet another
9 embodiment, as seen in Figure 6, the cocking seat may be pre-
10 introduced into housing, or be integrally formed with or secured
11 to the housing 20 such that the lancet 40 is effectively
12 maintained under a tension of the biasing assembly until
13 released by a moveable release assembly.

14 In particular, the present lancet device 10 further
15 includes a release element 56. In the illustrated embodiments,
16 the engagement element 45 of the engagement assembly preferably
17 has a generally flexible and/or resilient characteristic
18 relative to the lancet 40, and/or as will be described, includes
19 a single use pivot 46. As a result, when the cocking seat 30
20 and therefore the lancet 40 are urged sufficiently into an
21 interior 22 of housing 20, the release element 56 which also at
22 least partially extends into an interior of the housing 20 when
23 firing is desired, serves to engage the engagement element 45,
24 and ultimately causes upward movement thereof for disengagement
25 between the engagement element 45 and a retention lip 34.

1 Moreover, this disengagement is achieved after a substantial
2 amount of potential energy has been achieved in the biasing
3 assembly 50. As a result, disengagement between the lancet 40
4 and the cocking seat 30 results in the lancet 40 moving relative
5 to the cocking seat 30 under a force achieved by the potential
6 energy stored in the biasing assembly 50. The guide track 32
7 may also serve to guide generally linear movement of the lancet
8 40 relative to the cocking seat 30, as the lancet 40 moves to
9 the open interior 31 of the cocking seat 30 and ultimately
10 protrudes through an opening 37 in an exterior end 36 of the
11 cocking seat 30.

12 Looking further to the single use pivot 46, this may be
13 defined by a reduce thickness region in the segment that
14 ultimately defines the engagement element. The pivot 46 may be
15 seen to define a breakable hinge, and is configured such that
16 when the release element 56 engages the engagement element 45,
17 the engagement element 45 pivots on said pivot point and cannot
18 generally return to its pre-pivoted orientation. As a result,
19 even if re-positioning of the engagement element relative to the
20 cocking seat was attempted, the necessary engagement could not
21 be achieved as the reduced thickness portion snaps and or
22 deforms to prevent such re-positioning. A single use of the
23 device is therefor further ensured.

24 As previously indicated, the cocking seat 30, and
25 preferably the exterior end 36 of the cocking seat 30 may be

1 configured to engage a patient, at least in a general vicinity
2 of a portion to be pierced. Furthermore, in the preferred,
3 illustrated embodiment, the opening 37 at the end 36 of the
4 cocking seat 30 is preferably aligned with a specific location
5 to be pierced, such as on a tip of the finger. That portion of
6 the body, such as the finger, is thereby utilized as an abutment
7 on one of the lancet device 10, while a corresponding support
8 element, such as another finger or a thumb of the patient, or a
9 hand of a medical practitioner or other user, or a solid
10 surface, engages the housing 20 of the lancet device 10. In
11 this regard, as either or both the body section and the support
12 element are moved towards one another such that a spacing
13 therebetween is reduced, the moveable cocking seat 30 moves
14 further into the housing 20 until ultimately the engagement
15 element 45 engages and is released by the released element 56.
16 Once this release is achieved, the lancet 40 moves relative to
17 the cocking seat 30 passing, therethrough such that its piercing
18 tip 42 protrudes from the open end 37 of the cocking seat 30 and
19 piercingly engages the patient's skin. Therefore, in the
20 embodiments of Figures 1 and 2 the cocking movement directly
21 results in firing of the lancet 40, requiring only a single,
22 fluid movement to effectively utilize the present lancet device
23 10. Looking in further detailed to the previous description, it
24 is understood that the effective firing can be achieved either
25 by moving the portion of the patient, such as their finger

1 inward against a fixed support element, by moving a support
2 element towards a fixed portion of the body to be pierced and/or
3 by compressing both towards one another.

4 Turning to the embodiment of Figures 3 and 6, it is also
5 understood, that for further safety reasons, if desired, the
6 release element 56 may not necessarily be positioned at all
7 times in an appropriate location to effectively release the
8 lancet 40 from its engagement with the cocking seat 30. For
9 example, in the embodiment of Figure 3 a stopper 25 is position
10 such that movement of the cocking seat 30 and therefore the
11 lancet 40 towards the rear end 55' will not result in a
12 sufficient travel distance such that the engagement element 45
13 is released by the release element 56. Similarly, in the
14 embodiment of Figure 6 wherein the cocking seat forms part of
15 the housing and the lancet is re pre-cocked, but does not
16 automatically fire. Rather, in these illustrated embodiments
17 actuation of the rear end 55' inwardly is required so as to
18 effectively move the release element 56 into a position where it
19 may engage the engagement element 45 and provide for appropriate
20 release of the lancet 40 from the cocking seat 30. Also in the
21 embodiment of Figure 3 a spring or a stopper may be provided so
22 as to also restrict movement of the actuation element 55', as it
23 is ultimately preferred that actuation thereof be utilized only
24 so as to effectively position the release element 56 in a
25 position and orientation such that the previous or subsequent

1 movement of the cocking seat 30 and/or the housing 20 in the
2 manner previously described for cocking and firing results in
3 the releasing engagement between the release element 56 and the
4 engagement element 45. Also on such embodiments is recognized
5 that a variety of different actuation assemblies 55' may be
6 effectively provided so as to position the release element 56 in
7 its appropriate position to release the lancet. For example, a
8 side, spring loaded button and/or resilient button may be
9 provided such that the release element 56 is retained at least
10 partially out of the housing and/or out of engaging relation
11 with the engagement element 45 until it is actuated and moved at
12 least partially into the interior of the housing 20.
13 Furthermore, as evidenced by the embodiment of Figure 6,
14 additional structure may be provided so as to cock the lancet
15 device, or it may be sold pre-cocked with the cocking seat 30
16 may be pre-positioned in an appropriate position to allow
17 actuation of the release element 56 to effectively disengage the
18 engagement element 45 from the cocking seat 30. As mentioned, in
19 such an embodiment, the cocking seat 30 can be retained in
20 position relative to the housing or can merely be integrally
21 formed with and/or secured to the housing 20, thus eliminating
22 the need to push in the cocking seat 30 and allowing for mere
23 actuation of the release element 56 to result in disengagement
24 of a properly positioned engagement element.

25 Looking again to Figure 1, further features that may be

1 provided with the present invention may be the inclusion of a
2 cover element 43 which is structured to protect and shield the
3 piercing tip 42 of the lancet 40 prior to use. The cover
4 element 43 preferably extends out from the open interior 31 of
5 the cocking seat 30, out through the opening 37 so as to be
6 effectively grasped by a user for removal thereof when preparing
7 the lancet device 10 for use. Alternately, and exterior cover
8 that covers the cocking seat and/or surrounds the piercing tip
9 may also be provided. It is also noted, that the cocking seat
10 30 is configured such that even when the cover element 43 is
11 removed, the piercing end 42 is protected and/or shielded within
12 the interior 31 thereof unless and until use. Indeed, it is
13 only when the driving force of the biasing assembly 50 urges the
14 lancet's movement relative to the cocking seat 30 that the
15 piercing tip 42 temporarily passes through the opening 37.
16 Still, as a final safety measure, although a single biasing
17 assembly 50 may be sufficient so as to both drive the lancet 40
18 into its piercing orientation and so as to generally retract
19 back into its protective shielding within the cocking seat 30,
20 in some embodiments a secondary biasing assembly 52 may also be
21 positioned and interposed between the lancet 40 and the cocking
22 seat 30, the secondary biasing assembly 52 being structured and
23 disposed so as to not hinder movement of the piercing tip 42
24 into its piercing orientation, but so as to effectively retract
25 the lancet 40 back into its protective containment within the

1 cocking seat 30. Moreover, that retraction should not be
2 sufficient so as to return the lancet 40 into its engagement
3 relation with the cocking seat 30 for unitary movement
4 therebetween.

5 Since many modifications, variations and changes in detail
6 can be made to the described preferred embodiment of the
7 invention, it is intended that all matters in the foregoing
8 description and shown in the accompanying drawings be
9 interpreted as illustrative and not in a limiting sense. Thus,
10 the scope of the invention should be determined by the appended
11 claims and their legal equivalents.

12 Now that the invention has been described,